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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,580	06/26/2003	Nicholas A. Grippi	015445-9002-01	5786
23409	7590	12/13/2005	EXAMINER	
MICHAEL BEST & FRIEDRICH, LLP 100 E WISCONSIN AVENUE MILWAUKEE, WI 53202			HANLEY, SUSAN MARIE	
			ART UNIT	PAPER NUMBER

1651

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,580

Applicant(s)

GRIPPI ET AL.

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/26/03.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 18 pages. 1/29/04; 4/8/04; 8/23/04; 12/6/04; 12/13/04; 12/29/04; 9/2/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-16, drawn to a method for preparing a solid-fibrin web, classified in class 424, subclass 530, for example.
- II. Claims 17-41, drawn to a device for use in axial separation, classified in class 210, subclass 782, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case, a device for use in axial separation wherein the device comprises a primary chamber, a secondary chamber that contains a coagulator and a medium that separates said chambers can be used for other blood procedures for the isolation of any blood component including platelet-rich plasma, platelet concentrate, cryoprecipitated fibrinogen and other proteins within plasma such as thrombin and fibronectin (Holm, (US 5,795,489) col. 7, lines 10-47).

The several inventions listed above are independent and distinct from one another as they have acquired a separate status in the art and required independent searches, particularly with regard to the literature searches. Clearly, a reference which would anticipate one of the above groups would not necessarily anticipate or even make obvious the other group.

An undue burden would ensue from the examination of a device having multiple uses. Burden lies not only in the search of the US Patents, but in the search for literature and foreign patents and

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examination of claim language and the specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

Therefore, because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

If Group I is elected, the following specie elections are required:

A. Applicant is required to elect ONE cationic specie from magnesium, zinc, manganese or calcium.

If calcium is elected for the cationic specie, then Applicant is further required to elect ONE calcium specie from among those listed in claim 6.

B. Applicant is required to elect ONE therapeutic agent from among the species listed in claim 8.

i. If Applicant elects bone graft material as the therapeutic material, then Applicant is required to elect ONE of the bone graft subspecies listed in claim 11.

ii. If Applicant elects soft tissue graft as the therapeutic material, the Applicant is required to elect ONE of the materials listed in claim 12 .

iii. If Applicant elects an immunosuppressant as the therapeutic material, then Applicant is required to elect ONE of the following: an immunosuppressant for organ transplants or a cutaneous immunosuppressant.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, for the cationic specie election, claims 1-3 and 7-16 are generic. For the therapeutic agent election, claims 1-7, 15 and 16 are generic.

If Group II is elected, the following specie elections are required:

A. Applicant is required to elect ONE coagulator from magnesium, zinc, manganese or calcium.

If calcium is elected for the cationic specie, then Applicant is further required to elect ONE calcium specie from among those listed in claim 21 (which are the same as those in claim 35).

B. Applicant is required to elect ONE therapeutic agent from among the species listed in claim 31.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, for the coagulator election, claims 17, 18 and 22-32 and 36-41 are generic. For the therapeutic agent election, claims 1-30 and 32-41 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

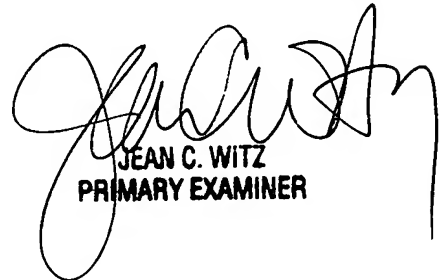
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Hanley
Patent Examiner
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JEAN C. WITZ
PRIMARY EXAMINER